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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/691,095

10/22/2003

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EXAMINER

JAGOE, DONNA A

ART UNIT

PAPER NUMBER

1614

NOTIFICATION DATE

DELIVERY MODE

09/02/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents\_Abbott\_Park@abbott.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/691,095	<b>Applicant(s)</b> BENNANI ET AL.	
	<b>Examiner</b> Donna Jagoe	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,10-14,22-31 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,10-14,22-31 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/24/04</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of the compound N-(2-amino-2-oxoethyl)spiro[2.5]octane-1-carboxamide in the reply filed on August 6, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

To Expedite prosecution, the claims indicated for cancellation are understood to be cancelled, however, Applicant is required to submit a proper amendment, listing those claims which are intended to be cancelled, as being cancelled.

Examination of the present claims was performed herein to the extent that the claims read upon the elected compound N-(2-amino-2-oxoethyl)spiro[2.5]octane-1-carboxamide and the method of using said compound. A reasonable comprehensive search by the Examiner has determined that the compound and methods of using said compound does not appear to be taught or suggested by the prior art.

For these reasons, the search and examination of the present claims has been extended to read upon the compound of formula II (claims 26-31) and methods of use comprising formula I (claims 1, 10-14, 22-25 and 39).

***Claims 1, 10-14, 22-31 and 39 are presented for examination.***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10-14, 22-31 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, claim 1 states that R<sub>2</sub> can be inter alia a "heterocycle or heterocyclealkyl, R<sub>3</sub> and R<sub>4</sub> can be heterocycle or heterocyclealkyl, R<sub>5</sub> and R<sub>6</sub> can be heterocycle or heterocyclealkyl and R<sub>8</sub> can be heterocycle or heterocyclealkyl. Claim 26 states that R<sub>3</sub> is a heterocycle or heterocyclealkyl, R<sub>4</sub> is a heterocycle or heterocyclealkyl, R<sub>5</sub> and R<sub>6</sub> can be a heterocycle or heterocyclealkyl, and R<sub>8</sub> can be a heterocycle or heterocyclealkyl. The word heterocycle and heterocyclealkyl fails to identify what is included or excluded in the compound. Different substituents in a pharmaceutical compound would imbue different activity. The word heterocycle implies a ring structure containing an atom other than carbon. Remington's Pharmaceutical Sciences teach that "many important biochemical compounds and drugs of natural origin contain heterocyclic ring structures. Numerous examples occur e.g., among the carbohydrates essential amino acids, vitamins, alkaloids, glycosides, antibiotics, etc.

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The presence of heterocyclic structures in such diverse types of compounds is strongly indicative of the profound effects such structures exert on physiological activity and recognition of this is abundantly reflected in efforts to find useful synthetic drugs" (page 411, column 1). These facts are easily confirmed by table VI (pages 412-415), for example, see a 2,5-dihydrofuran which includes ascorbic acid and digitoxin and a similar tetrahydrofuran that includes streptomycin and sucrose (page 412, column 1). These structures are similar, however the activity of these structures are varied.

The specification as originally filed contains the following disclosures concerning heterocycles and heterocyclealkyls:

"The term "heterocycle" or "heterocyclic" as used herein, means a monocyclic, bicyclic, or tricyclic ring system. Monocyclic ring systems are exemplified by any 3- or 4-membered ring containing a heteroatom independently selected from the group consisting of oxygen, nitrogen and sulfur; or a 5-, 6- or 7-membered ring containing one, two or three heteroatoms wherein the heteroatoms are independently selected from the group consisting of nitrogen, oxygen and sulfur. The 5-membered ring has from 0-2 double bonds and the 6- and 7-membered ring have from 0-3 double bonds.

Representative examples of monocyclic ring systems include, but are **not limited to**, azetidiny, azepany, aziridiny, diazepiny, 1,3- dioxolany, dioxany, dithianyl, furyl, imidazolyl, imidazoliny, imidazolidiny, isothiazolyl, isothiazoliny, isothiazolidiny, isoxazolyl, isoxazoliny, isoxazolidiny, morpholiny, oxadiazolyl, oxadiazoliny, oxadiazolidiny, oxazolyl, oxazoliny, oxazolidiny, piperaziny, piperidiny, pyranyl, pyraziny, pyrazolyl, pyrazoliny, pyrazolidiny, pyridiny, pyrimidiny, pyridaziny, pyrrolyl,

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pyrrolinyl, pyrrolidinyl, tetrahydrofuranyl, tetrahydrothienyl, tetrazinyl, tetrazolyl, thiadiazolyl, thiadiazolinyl, thiadiazolidinyl, thiazolyl, thiazolinyl, thiazolidinyl, thienyl, thiomorpholinyl, 1,1-dioxidothiomorpholinyl (thiomorpholine sulfone), thiopyranyl, triazinyl, triazolyl, and trithianyl. Bicyclic ring systems are exemplified by any of the above monocyclic ring systems fused to an aryl group as defined herein, a cycloalkyl group as defined herein, or another monocyclic ring system. Representative examples of bicyclic ring systems include but are **not limited to**, for example, benzimidazolyl, benzodioxinyl, benzothiazolyl, benzothienyl, benzotriazolyl, benzoxazolyl, benzofuranyl, benzopyranyl, benzothiopyranyl, cinnolinyl, indazolyl, indolyl, 2,3-dihydroindolyl, indolizinyl, naphthyridinyl, isobenzofuranyl, isobenzothienyl, isoindolyl, isoquinolinyl, phthalazinyl, pyranopyridinyl, quinolinyl, quinolizinyl, quinoxalinyl, quinazolinyl, tetrahydroisoquinolinyl, tetrahydroquinolinyl, and thiopyranopyridinyl. Tricyclic ring systems are exemplified by any of the above bicyclic ring systems fused to an aryl group as defined herein, a cycloalkyl group as defined herein, or a monocyclic ring system. Representative examples of tricyclic ring systems include, but are **not limited to**, acridinyl, carbazolyl, carbolinyl, dibenzo[b,d]furanyl, dibenzo[b,d]thienyl, naphtho[2,3-b]furan, naphtho[2,3-b]thienyl, phenazinyl, phenothiazinyl, phenoxazinyl, thianthrenyl, thioxanthenyl and xanthenyl. The heterocycles of this invention are optionally substituted with 1, 2, or 3 substituents independently selected from the group consisting of alkenyl, alkoxy, alkoxyalkoxy, alkoxyalkyl, alkoxycarbonyl, alkoxycarbonylalkyl, alkoxysulfonyl, alkyl, alkylcarbonyl, alkylcarbonylalkyl, alkylcarbonyloxy, alkylthio, alkylthioalkyl, alkynyl, carboxy, carboxyalkyl, cyano,

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cyanoalkyl, ethylenedioxy, formyl, haloalkoxy, haloalkyl, halogen, hydroxy, hydroxyalkyl, mercapto, methylenedioxy, nitro, oxo, -NRDRE, and (NRDRE)carbonyl. The term "heterocyclealkyl" as used herein, means a heterocycle, as defined herein, appended to the parent molecular moiety through an alkyl group, as defined herein. Representative examples of heterocyclealkyl include, but are **not limited to**, pyridin-3-ylmethyl and 2-pyrimidin-2-ylpropyl. ." (pages 20-21);

The above disclosures, however, do not provide adequate support for compounds and method of using said compounds for treating migraine, epilepsy or bipolar disorder (claims 1 and 10-14), a method of treating pain, a movement disorder or psychiatric disorder (claims 22-23), a method of providing neuroprotection in a mammal (claims 24-25) and a method of treating neuropathic and inflammatory pain in a mammal (claim 39).

### **Written Description**

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention.

*Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The Examiner is guided in his opinion that Applicant has not adequately described the presently claimed subject matter by the MPEP at § 2163 - 2163.05. In particular, while Applicant's specification as originally filed contains a generic disclosure of some examples of heterocycles, there are numerous statements that the structure is "not limited to" the examples cited. "A lack of adequate written description issue also

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arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996)"(emphasis added), see MPEP § 2163(I)(A). Considering the teachings provided in the specification as originally filed, the Examiner finds that Applicants have failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set for the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicants had possession of the concept of a heterocycle or heterocyclealkyl in any of the R<sub>2</sub>-R<sub>6</sub> and R<sub>8</sub> substituents of formula I.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./  
Examiner  
Art Unit 1614

August 12, 2009

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614